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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,388	ZERBE ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-51* is/are pending in the application.

4a) Of the above claim(s) *41-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *A-B*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claims 41-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 3, 2006. The Applicant argues the manufacturing process recited by the claims and the process recited by the Examiner is not a materially different process. This argument is not persuasive. Changing the order of the process may make the composition more uniform it can also effect the time it takes to make the composition. In regards to Groups I and III, the Applicant argues because the claims recite a mucoadhesive, the composition cannot be applied to the skin. This argument is not persuasive because although the composition is characterized as a mucoadhesive does not mean it cannot be use on the skin. Compounds used as mucoadhesives are also used on other surfaces besides the mouth. The restriction is proper and made FINAL.

Claims

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-29, 31, 33-35, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith et al. (US 4,764,378).

Keith et al. teach dosage forms for administration of drugs and more particularly buccal dosage forms having a polymeric matrix for controlled release of a drug. The composition comprises three essential ingredients: from about 20% to about 75% by weight of a low molecular weight polyethylene glycol component, from about 2% to about 65% by weight of a medium or high molecular weight polyethylene glycol component, and from about 1% to about 40% by weight of an auxiliary high molecular weight polymer. The dosage forms include disks, wafers, tablets, lozenges, lamellae and the like. Suitable high molecular weight polymers include polyvinylpyrrolidone (PVP), polyethylene oxide (PEO), poly(acrylic acid) (PAA), sodium alginate and carboxymethyl cellulose, which encompasses claim 31. Preferred high molecular weight polymers include polyvinyl pyrrolidone and polyethylene oxide. Both of these polymers provide the matrix with water-activated adhesive properties for good adhesion to the oral mucosa. The polymers are incorporated into the compositions at concentrations ranging fro about 25% to about 40% encompassing claim 33. The dosage form rapidly disintegrates and dissolves after being placed in the mouth, encompassing the instant claims (col. 4, lines 1-20). Additional ingredients may be incorporated into the buccal matrix of the invention to provide desirable physical properties or modify the properties of the matrix (col. 4, lines 28-33), encompassing claims 34-35. For example, a plasticizer such as propylene glycol may be added in

amounts up to about 5% by weight of the matrix. Preferred drugs for incorporation into the buccal dosage form include nicotine (col. 5, line 30). The active ingredient will generally comprise from about 0.01 percent by weight to about 10 percent by weight of the dosage form (col. 5, lines 40-44), encompassing claim 38. Suitable dimensions for the dosage form are a length of 5 to 10 mm, a width of 2 to 10 mm and a thickness of 0.2 to 3 mm (col. 6, lines 1-9), encompassing claim 29. Lamellae dosage forms with a certain composition dissolved rapidly when placed in the buccal pouch or sublingually (col. 6, lines 33-35). A small amount of a dye may also be incorporated into the matrix. The reference anticipates the instant claims insofar as it teaches a monolayer film comprising one or more water-soluble polymers, and nicotine.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (US 5,354,551).

Schmitt teaches oral care films comprising tensides (surfactants), polishing agents, aromatizing substances (flavoring oils), sweetening agents, active agents and binding agents or a mixture of binding agents which consist of water-soluble or water-swellable, physiologically acceptable film forming substances. Film forming agents include starch, gelatins, glycerols and/or sorbite as well as natural and synthetic resins and gums. Active agents include antibacterial agents, which are considered pharmaceutical active agents. Aromatizing substances include menthol, peppermint, spearmint oil and cinnamon oil. Sweetening agents include aspartame and plasticizers include sorbitol. The films have a thickness of between 0.1 to 3 mm. The reference differs from the instant claims insofar as it does not teach using more than one surfactant in the oral films although it does teach different surfactants individually. Case

law supports, generally, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069,1072 (CCPA 1980); In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960). It would have been obvious to one of ordinary skill in the art to have combined the individual surfactants to form different mixtures consonant with this reasoning.

2) Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (US 5,354,551) in view of Story et al. (US 4,944,949).

Schmidt, the primary reference is discussed above. The reference differs from the instant claims insofar as it does not teach using more than one surfactant.

Story et al. teach pharmaceutical delivery systems comprising drugs formulated with surfactants (see abstract). The surfactant is used to dissolve the drug. Surfactants can be variously classified, and often by reference to the nature of the hydrophilic region, which can be anionic, cationic, zwitterionic or nonionic. The preferred surfactants of the reference are nonionic surfactants, which include polyoxyethylated surfactants, including polyoxyethylated glycol monoethers, polyoxyethylated fatty acids, polyoxyethylated sorbitan fatty esters, and polyoxyethylated castor oils. However, other nonionic surfactants are also particularly appropriate, including sorbitan fatty acid esters, poloxamers, polyethylene glycol fatty acid esters and polyethoxylated glyceryl

fatty acid esters. Whatever the precise chemical structure of the surfactant or surfactants used, it is generally preferred to use one or more of those that have been already cleared for human ingestion. Therefore, surfactants with a low toxicity are preferred. One factor affecting the choice of surfactant or surfactants to be used is the hydrophilic-lipophilic balance (HLB), which gives a numerical indication of the relative affinity of the surfactant for aqueous and non-aqueous systems. There may be cases where a mixture of two or more surfactants provides an improved degree of solubilization over either surfactant used alone. Additional components may be added to the compositions such as preservatives, sweeteners and flavoring agents. The reference differs from the instant claims insofar as it does not teach the oral compositions as a monolayer film or the oral compositions comprising water-soluble polymers.

It would have been obvious to one of ordinary skill in the art to have used the more than one surfactant in the films of the primary reference motivated by the desire to obtain a uniform dispersion of the pharmaceutically active agent by optimizing solubility of the active agent in the surfactant system as taught by the secondary reference.

3) Claims 11-12, 14-18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (US 5,354,551) as applied to claims 10 and 13 above, and further in view of Acharya (US 5,686,094).

The primary reference is discussed above. The reference differs from the instant claims insofar as it does not teach flavor enhancers, colorants and particular sweeteners such as aspartame and sorbitiol.

Acharya teaches polymeric delivery systems which can be used in the oral cavity. The compositions' controlled release rate of the active agent is dependent upon the structure of the polymeric matrix, which may be modified through use of water, polar and nonpolar co-solvents, by varying their amounts and the inclusion of other components, e.g. carbohydrates and hydrocolloids which act to modify the physical and chemical properties of the matrix. For example, an auxiliary hydrocolloid may be employed, such as cellulose polymers, which are cellulose ethers including methylcellulose, cellulose alkyl hydroxylates such as hydroxypropylmethyl cellulose, hydroxypropyl cellulose, hydroxymethyl cellulose or hydroxyethyl cellulose, cellulose, gum xanthan, alkali metal or alkaline earth metal carageenates or mixtures thereof. Simple or complex carbohydrates or polyols, such as sucrose, xylose, mannitol, glucose, starch, Pluronic® surfactants, inorganic salts such as dicalcium phosphate, and the like, may also be employed to modify the hydrogel structure. The compositions of the invention may optionally include one or more excipients in an amount within the range of from about 0.1% to about 99% by weight and preferably from about 1% to about 95% by weight, such as sorbitol. Other conventional ingredients, which may optionally be present, include preservatives, stabilizers, plasticizers, co-solvents, anti-adherents or silica flow conditioners as well as FD&C colors. Other ingredients that can be present in the compositions include breath fresheners and flavors, e.g., spearmint

oil, peppermint oil, cinnamaldehyde, cetyl pyridinium chloride, menthol and tartaric acid, which is a flavor enhancer. The reference differs from the instant claims insofar as it does not teach using two surfactants in the compositions and the dimensions of the films.

It would have been obvious to one of ordinary skill in the art to have used the additives in the films of the primary reference motivated by the desire to obtain a enhance the flavor and make the films aesthetically pleasing as taught by the secondary reference.

4) Claims 24-27 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (US 4,764,378) in view of Acharya (US 5,686,094).

Keith et al., the primary reference is discussed above and teaches delivering nicotine by buccal dosage forms. The reference differs from the instant claims insofar as it does not teach incorporating, flavors, flavor enhancers and surfactants although it does teach additional ingredients may be incorporated into the buccal matrix of the invention to provide desirable physical properties or modify the properties of the matrix.

Acharya, the secondary reference, is discussed above and teaches polymeric delivery systems which can be used in the oral cavity comprising flavors, flavor enhancers and sweeteners such as sorbitol. The reference differs from the instant claims insofar as it does not teach the disk or lamellae comprise nicotine.

It would have been obvious to one of ordinary skill in the art to have used the additives in the films of the primary reference motivated by the desire to obtain a

enhance the flavor and make the films aesthetically pleasing as taught by the secondary reference.

5) Claims 28, 30 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (US 4,764,378) in view of Stanley et al. (US 5,783,207).

Keith et al., the primary reference is discussed above and teaches delivering nicotine by buccal dosage forms. The reference differs from the instant claims insofar as it does not teach incorporating nicotine salts, flavors, flavor enhancers and surfactants although it does teach additional ingredients may be incorporated into the buccal matrix of the invention to provide desirable physical properties or modify the properties of the matrix.

Stanley et al. teach dosage forms comprising nicotine and its salts. Nicotine is released from a dosage form and absorbed through the intra-oral mucosal surfaces as the nicotine-containing matrix releases nicotine within the user's mouth. Nicotine is available in either the free base or salt form. Nicotine base is readily absorbed through mucosal membranes but is highly volatile. Nicotine salts, on the other hand, are not readily absorbable through mucosal membranes but are much more stable. Pharmaceutically acceptable nicotine salts include, but are not limited to nicotine hydrochloride and nicotine salicylate. In an alkaline environment, i.e., pH above about 7, and in the presence of an aqueous medium, such as saliva within the oral cavity, nicotine salts react to form nicotine base. In addition to nicotine in a releasable form, which is readily absorbed transmucosally; the nicotine-containing

compositions in accord with the present invention may contain other ingredients such as flavorings, sweeteners, flavor enhancers, lubricants, binders and fillers. The reference differs from the instant claims insofar as it does not teach the matrices as being able to rapidly disintegrate or soften immediately.

It would have been obvious to one of ordinary skill in the art to have used the nicotine salts and other ingredients in the compositions of the primary reference motivated by the desire to produce a dosage form wherein the active ingredient was stable as disclosed by the secondary reference.

6) Claims 20 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (US 4,764,378) in view of Story et al. (US 4,944,949).

Keith et al., the primary reference is discussed above and teaches delivering nicotine by buccal dosage forms. The reference differs from the instant claims insofar as it does not teach incorporating surfactants into the oral compositions although it does teach additional ingredients may be incorporated into the buccal matrix of the invention to provide desirable physical properties or modify the properties of the matrix.

Story et al., the secondary reference, is discussed above and teaches using a mixture of surfactants in pharmaceutical compositions. The compositions may also comprise flavoring agents and sweeteners. The reference differs from the instant claims insofar as it does not teach the oral compositions as a monolayer film or the oral compositions comprising water-soluble polymers comprising nicotine.

It would have been obvious to one of ordinary skill in the art to have used the surfactants and mixtures thereof in the compositions of the primary reference motivated by the desire to ensure a uniform mixture throughout the film thoroughly dissolve the drug being incorporated into the film as taught by the secondary reference.

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 10-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,948,430 in view of Stanley et al. (US 5,288,497). The claims are coextensive because the compositions of the instant claims are species of the patent. The claims of the patent are broader and all the components found in the compositions of instant claims do not

necessarily have to be in the compositions of the patent, they are optional. Stanley teaches dissolvable matrixes that comprise an active agent. One of the active agents is nicotine. The systems comprise ingredients such as surfactants, sweeteners, colorants flavorings, flavor enhancers and preservatives. These ingredients made the drug containing dosage form desirable, for example, having a good taste as provided by the flavorings. The reference differs from the instant claims insofar as it does not teach a monolayer film.

It would have been obvious to one of ordinary skill in the art to have added these components in combination with one because the components add a property to the dosage form to make it a more desirable medication, as taught by the secondary reference.

2) Claims 10-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,177,096 in view of in view of Keith et al. (US 4,764,378). The claims are coextensive insofar as they both teach compositions comprising a water-soluble polymer, surfactants and active ingredients for the oral cavity. The patent differs from the instant claims insofar as it teaches various types of pharmaceutical actives that may be incorporated into the compositions whereas the instant claims are broader such as the case in instant claim 10. The patent also incorporates plasticizers into the compositions. Keith et al. teach dosage form compositions comprising plasticizers such as propylene glycol may be added to provide a desirable physical property to the oral compositions, such as serving

as a solvent for the polymers. The compositions may be used to deliver various types of active agents (see col. 5 for list of active agents).

It would have been obvious to one of ordinary skill in the art to have added a polyalcohol to the compositions and incorporate the different active agents in the compositions of the instant claims motivated by the desire dissolve the polymer as taught by the secondary reference.

3) Claims 10-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-15 of U.S. Patent No. 6,592,887 in view of Keith et al. (US 4,764,378). The claims are coextensive because the compositions of the instant claims and the claims of the patent both read on films that comprise nicotine or a nicotine salt. The instant claims are more specific as to what type of water-soluble polymer may be used in the compositions. Keith et al. teach control release compositions comprising nicotine. Polymers used in the compositions include polyvinylpyrrolidone (PVP), polyethylene oxide (PEO), poly(acrylic acid) (PAA), sodium alginate and carboxymethyl cellulose. These polymers provide the matrix with water-activated adhesive properties for good adhesion to the oral mucosa.

It would have been obvious to have used the water-soluble polymers of instant claims in the compositions of the patent motivated by the desire to provide a film with good adhesion to the oral mucosa, as taught by the secondary reference.

4) Claims 10-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,709,671 in view of Keith et al. (US 4,764,378). The claims are coextensive insofar as they both teach monolayer films comprising a water-soluble polymer with the films having similar dimensions. The films may also comprise flavorings, a pharmaceutical ingredient and comprise oral hygiene components. The claims differ insofar as the patent compositions comprise a polyalcohol in combination with a surfactant. Keith et al. teach dosage form compositions comprising plasticizers such as propylene glycol may be added to provide a desirable physical property to the oral compositions, such as serving as a solvent for the polymers.

It would have been obvious to one of ordinary skill in the art to have added a polyalcohol to the compositions of the instant claims motivated by the desire dissolve the polymer as taught by the secondary reference.

Claims 10-40 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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